

provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3-8-55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4747. (F. D. C. No. 29458. S. Nos. 15-860 K, 41-953/4 K, 41-964/5 K, 60-679/80 K.)

INFORMATION FILED: 9-11-50, E. Dist. Wis., against Lyon Drug Co., a partnership, Milwaukee, Wis., and Walter G. Kopling, a partner.

CHARGE: Between 10-17-49 and 12-19-49, 3 sales of *Seconal Sodium capsules* and 4 sales of *Nembutal capsules* were made by the defendants without obtaining a physician's prescription, which acts resulted in the drugs being misbranded as follows: 502 (b) (2)—each drug failed to bear a label containing a statement of the quantity of contents; 502 (d)—each drug contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning: May be habit forming"; and 502 (f) (1)—the labeling of each drug failed to bear adequate directions for use.

DISPOSITION: On 10-9-50, the defendant filed a motion to suppress evidence. The matter came on for hearing before the court on 3-1-54; and, on 6-25-54, the court handed down the following opinion in denial of the motion:

TEHAN, *District Judge*: "The defendants, Lyon Drug Company, a partnership, and Walter G. Kopling, the manager and one of the partners, are charged in seven counts of an Information with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. 331, et seq., particularly Section 331 (k). The defendants have now moved to suppress certain evidence and have it returned to them on the ground that it was seized in violation of their constitutional rights, and in violation of an immunity clause in Section 373 of the statute itself.

"The defendants allege in their motion that the evidence, consisting of information, data, drugs, labels and prescriptions, and obtained by two inspectors of the United States Food and Drug Administration, was obtained without a search warrant and without voluntary permission of any person authorized to give such permission, and that it was given only because the inspectors represented that they had the right under the law to receive and remove such information and material. Both the Government and the defendants filed affidavits relating the facts as to the manner in which the Government obtained the evidence in question. Although the allegations of the affidavits filed by the opposing parties were not in substantial conflict, the Court ordered a hearing on the motion for the purpose of taking testimony.

"The testimony of Frank Thompson, Jr. and Charles C. Curry, who were employed as inspectors by the United States Food and Drug Administration, showed that they visited the defendants' drug store on December 20, 1949, during the usual business hours, for the purpose of conducting an inspection. They had visited the place several times previously getting refills on prescriptions. On this particular occasion when Curry was refused a refill on a prescription, he left the store momentarily, and then re-entered with Thompson. They introduced themselves as United States Food and Drug inspectors to the defendant, Kopling, showed him their credentials and stated that they wished to examine the files, pharmaceuticals, invoices and prescriptions. At their request, Kopling, without objection, or protest, allowed them to examine his drug inventory, invoice files, and prescription files, and provided them with drug samples and certain prescriptions which they requested from his files. In addition, he signed a statement which identified the drug samples as having come from the same bottles used in refilling the prescriptions and which also indicated the source from which he had received the drugs. Thomp-

*See also Nos. 4741-4746.

son and Curry further testified that Kopling willingly, cooperatively, and courteously provided them with everything which they requested.

"Kopling's testimony, together with the testimony of his pharmacist, Joel D. Leslie, was substantially the same as that of Thompson and Curry, and Kopling himself testified that he raised no objection to the search that the inspectors desired to make, and in fact stated that he was 'very cooperative' and that he had 'cooperated fully.' He further testified that there was never a 'demand' for the information on the part of the inspectors, and explained his position at the time of the inspection by stating that if a policeman came up to him and showed credentials, he, Kopling, would certainly answer any questions asked of him.

"The defendants' motion to suppress the evidence is based, first, upon their contention that any evidence obtained by the inspectors on December 20, 1949, was obtained under duress and should therefore be returned.

"The Court believes that the defendants' first contention to the effect that the evidence was taken under duress is not supported by the credible evidence in the case. The Court is convinced that the defendants made no objection to the inspection, and that the defendant, Kopling, acting both for himself and for the partnership, at the request of the inspectors, opened his files and records, and freely made available to them the samples, information, and papers, which the defendants now seek to suppress. Kopling not only consented willingly to the inspection, but, by his own testimony, was completely cooperative throughout, and aided and assisted the agents in their search. The record shows that he voluntarily signed statements relating to the receipt and sale of the drugs, that he searched his files and located and turned over to the inspectors certain prescriptions requested by them, and that he voluntarily sold them samples of drugs and accepted payment therefor.

"Defendants' position that duress existed rests primarily upon the fact that the inspectors introduced and identified themselves as Government agents before making their requests for information. That fact alone under the circumstances of this case is not sufficient to constitute duress. In the absence of any threats, intimidation or force, incriminating matter turned over to law enforcement officials by an accused may be used in evidence against him. *Zapp v. United States*, 328 U. S. 624 (1946); *United States v. MacLeod*, 207 F. 2d 853 (C. A. 7 1953).

"The second and final contention of the defendants is that the inspection and collection of samples was made pursuant to Title 21 U. S. C. A. Section 373, and that consequently they are entitled to the immunity provided by such section. Section 373 provides as follows:

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, That carriers shall not be subject to receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.* [Emphasis added.]

"The Court is of the opinion that this section is not applicable and consequently that the defendants' argument is without merit. First, it should be noted that Title 21 U. S. C. A. Sections 372 and 374 also authorize the type of an inspection, investigation and collection of samples conducted in the instant case, and secondly, since the information sought in the instant case was provided voluntarily by the defendants, it was not necessary to proceed under the statutory provisions of Section 373.

"The reason for the enactment of Section 373 is clearly indicated by its legislative history. The committee report which accompanied the Bill (H. R. Rep. #2139, 75th Cong., Third Session, 1938) states in part:

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. * * * The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception * * *. Carriers are required to make available, for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established * * *. Section 703 (373) required interstate carriers and receivers to permit access to and the copying of all necessary records to show interstate shipment and thus establish Federal jurisdiction. This provision is necessary since some warehousemen and trucking concerns and even some railroads have refused to permit the copying of records which were essential to the institution of proceedings to control abuses of consumer health and welfare. The absence of such provision in the present law has been a definite handicap to its enforcement * * *. In short, the purpose of the provision here in question was to close an earlier loophole in the enforcement provisions of the act, which handicapped its enforcement, this handicap being caused by the refusal of certain carriers, if not others, to permit the copying of essential records. In other words, where, as was generally the case, these records were willingly made available to the Government, so that the Act could readily be enforced, the previous law was effective. But, in cases where this access and copying was refused, the section in question would apply to overcome such refusal, and eliminate such "handicap to its (the Act's) enforcement."

"The purpose in enacting Section 373, as is clearly indicated by the legislative history, was to enable the enforcement officials to obtain records of interstate shipment so that Federal jurisdiction could be established, and by its very terms, Section 373 is confined to records of interstate shipment.

"The defendants argue that they were placed in a position where if they refused to consent to the inspection they would be guilty of a misdemeanor (Title 21 U. S. C. A. 331 (e)), whereas by consenting to it they find themselves charged with a felony. However, as the section itself indicates, it is not a violation of law to refuse to allow inspection of interstate records upon a simple request of an inspector. It becomes unlawful only 'when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device or cosmetic to which such request relates.'

"The defendants' motion and arguments in support thereof are similar to those raised in the case of *United States v. Arnold Pharmacy*, 116 F. Supp. 310, 314. In that case the Court said:

Considered, therefore, in the light of both the purpose of this statutory amendment and of its terms, it is clear that it is not intended to hamper the powers of the Government in protecting the public, but to add to its powers to that end. Thus since, under well settled principles, those who voluntarily turn over their records to the Government cannot object to their use in criminal proceedings, it can hardly be claimed that this statutory amendment was intended to prevent such use under such circumstances. On the other hand, it is clear both from the purpose of the amendment and its terms, that the section was intended to apply where access to the records was refused the Government. In that event, by proceeding under the statutory provision in question, the Government could obtain access to such records despite such refusal. But, if the Government did so proceed, then the "evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained."

"The Court is of the opinion that the evidence here in question was voluntarily turned over to the inspectors by its owners, that the conditions for the applicability of Section 373 did not exist, and that the Statute does not apply. The Court believes that *United States v. Crescent-Kelvan Co.*, 164 F.2d 582 (C. A. 3 1948) and *United States of America v. Scientific Aids Co., a partnership, et al.* (Cr. 268-53, U. S. Dist. Court, N. J., Jan. 19, 1954) support this view.

"Defendants' motion to suppress the evidence must therefore be denied."

On 10-12-54 a plea of guilty was entered by the partnership to counts 1, 2, 3, and 4 of the information and, by agreement of the parties, the charges against the partnership on counts 5, 6, and 7 and against the individual on all counts were dismissed. On 12-20-54, the court fined the partnership \$700.